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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,263	04/13/2004	Paul P. Latta	LATTA.002C4	3489

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/823,263

Applicant(s)

LATTA, PAUL P.

Examiner

Michail A. Belyavskiy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 05/09/05 is acknowledged.

Claims 1-14 are pending.

Claims 1-14 are under consideration in the instant application.

Applicant's amendment filed 05/09/05 in conjunction with Declaration of Dr. Scharp under 37 C.F.R. 1.132 demonstrating the effectiveness of implantation of a sub-therapeutic, tolerizing dose of insulin-secreting cells and further administering an therapeutic dose of insulin-secreting cells to treat diabetes, has obviated the previous enablement rejection under 35 U.S.C. 112, first paragraph.

In view of the amendment, filed 05/09/05 the following rejections remain:

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4 and 6 -14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,703,017 or by US Patent 5,425,764 or US Patent 5,629,194 each in view Posselt et al (Diabetes, 1992, v.41, pages 771-775) for the same reasons set forth in the previous Office Action, mailed on 01/26/05.

Applicant's arguments, filed 05/09/05 have been fully considered, but have not been found convincing.

Applicant asserts that: (i) US Patent '017 requires implanting only therapeutic dose of insulin-secreting cells and does not suggest implanting a tolerizing dose of insulin-producing cell prior to implanting of fully therapeutic dose; (ii) US Patent '194 does not describe or suggest implanting of a tolerizing dose of insulin producing cells prior to implanting of fully therapeutic dose; (iii) Posselt et al., teaches away from using tolerizing dose of insulin producing cells anywhere but thymus.

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Applicants have traversed the primary and the secondary references pointing to the differences between the claims and the disclosure in each reference. Applicant is respectfully reminded that the rejection is under 35 USC103 and that unobviousness cannot be established by attacking the references individually when the rejection is based on the combination of the references. see *In re Keller*, 642 F.2d 4B, 208 USPQ 871, 882 (CCPA 1981) See MPEP 2145. This applicant has not done, but rather argues the references individually and not their combination. One cannot show non-obviousness by attacking references individually where the rejections are based on a combination of references. *In re Young* 403 F.2d 759, 150 USPQ 725 (CCPA 1968).

As has been stated previously, US Patent '017 teaches a method of treating diabetes in a mammal comprising implanting insulin-producing cells encapsulated in a biologically compatible membrane (see entire document, Abstract and columns 6, 8, 9 –14 and Example 12 in particular) . US Patent '017 teaches that insulin producing cells are pancreatic islet cells from primary cell source (see columns 8 and 11 in particular). US Patent '017 teaches that pancreatic islet cells are from the same species as the mammal and are implanted interperitoneally into the tissue of a mammal beneath the kidney capsule (see overlapping columns 13-14 and Example 2 in particular). US Patent '017 teaches that encapsulation of said insulin-producing cells in biologically compatible membrane for success of implantation is well known in the art (see column 12 and Example 12 in particular).

US Patent '764 teaches a method of treating diabetes in a mammal comprising implanting insulin-producing cells encapsulated in a biologically compatible membrane (see entire document, Abstract and overlapping columns 5-6 in particular). US Patent '764 teaches that insulin producing cells are pancreatic islet cells (see column 1 and 4 in particular). US Patent '764 teaches that cells are implanted interperitoneally (see column 5 in particular).

US Patent '194 teaches a method of treating diabetes in mammal comprising implanting insulin-producing cells encapsulated in a biologically compatible membrane (see entire document, Abstract overlapping columns 7-8 , 12 and Example II in particular). US Patent '764 teaches that insulin producing cells are pancreatic islet cells (see column 8 in particular). US Patent '764 teaches that cells are implanted intaportal (see column 7 in particular). US Patent '194 teaches administration of one or more anti-inflammatory agent at the dosage sufficient to achieve the desired therapeutic effect. US Patent '194 teaches that said agent can be administered prior to at the same time or subsequent to administration of insulin-producing cells (see overlapping columns 14-15 in particular).

US Patent '017 or US Patent ' 764 or US Patent '194 does not explicitly teaches a method of treating diabetes in a mammal comprising administration two doses of insulin-secreting cells one tolerizing and one curative wherein tolerizing doze is one order less than curative.

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With regards to the issue that Posselt et al., teaches away from using tolerizing dose of insulin producing cells anywhere but thymus. The Examiner disagrees with Applicant's interpretation of Posselt et al. Moreover, it is noted that the instant claims does not recited any specific place where a tolerizing dose of insulin-secreting cells should be implanting. It is the Examiner position that Posselet et al., teach that the important goal in the treatment of insulin-dependent diabetes by pancreatic islet transplantation is the development of strategies that allow permanent survival of pancreatic islet without continuous host immunosuppression. Posselet et al., further teach a strategy comprising two step process : first administering a small dose of cells that induces an unresponsive state, i.e. tolerizing dose and then administering fully therapeutic dose, at another site (see entire document, Abstract in particular). Posselet et al., teach that said strategy permits the survival of pancreatic islet transplant.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Posselt at al. to those of US Patent '017 or US Patent ' 764 or US Patent '194 to obtain a claimed method of treating diabetes in a mammal comprising administration two doses of insulin-secreting cells one tolerizing and one curative wherein tolerizing doze is one order less than curative

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because a strategy comprising two step process : first administering a small dose of cells that induces an unresponsive state, i.e. tolerizing dose and then administering fully therapeutic dose, at another site permits the survival of pancreatic islet transplant as taught by Posselet et al. Said strategy can used in the method of treating diabetes in a mammal, comprising implanting pancreatic islet, taught by US Patent '017 or US Patent ' 764 or US Patent '194. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 8-14 are included because it would be conventional and within the skill of the art to : (i) determine the proper pore size for the permselective membrane or (ii) to determine the optimum dosage and means of administration of insulin-secreting cells in an absent of a showing of unobvious property. Moreover, Applicant acknowledge that one of ordinary skill in the art can readily determine the proper pore size for the permselective membrane (see page 8, line 13-20

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of the instant Specification in particular). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges or means of administration involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

4. Claim 5 stands rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,703,017 or by US Patent 5,425,764 or US Patent 5,629,194 each in view Posselt et al (Diabetes, 1992, v.41, pages 771-775) as applied to claims 1-4 and 6-14 above, and further in view of US Patent 5,529,914 for the same reasons set forth in the previous Office Action, mailed on 01/26/05.

Applicant's arguments, filed 05/09/05 have been fully considered, but have not been found convincing.

Applicant asserts that because US Patent 6,703,017, US Patent 5,425,764 US Patent 5,629,194 and Posselt et al., are not prior art and do not suggest the claimed invention they can not be used in combination with US Patent 5,529,914.

As have been discussed, supra, it is the Examiner position that the prior art of US Patent 6,703,017, US Patent 5,425,764 US Patent 5,629,194 and Posselt et al., do suggest the claimed invention and thus can be used in combination with US Patent 5,529,914.

The combined references do not explicitly teach a method of treating diabetes in a mammal comprising implanting insulin-secreting cells, wherein insulin-secreting cells are encapsulated in a biologically compatible membrane wherein said membrane comprises polyethylene glycol (PEG).

US Patent '914 teaches a new type of biocompatible membrane as a covering to encapsulate biological materials, comprising PEG that is acceptable for implants in mammalian. (see entire document, Abstract in particular). US Patent '914 teaches that various types of cells can be encapsulated in said biocompatible membrane and that said encapsulation will prevent rejection of encapsulated cells during transplantation (see column 10 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '914 to those of US Patent " 017, US Patent ' 764 , US Patent' 194 and Posselt et al., to obtain a claimed method of treating diabetes in a mammal comprising implanting insulin-secreting cells, wherein insulin-secreting cells are encapsulated in a biologically compatible membrane wherein said membrane comprises polyethylene glycol (PEG).

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One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because encapsulation of cells in biologically compatible membrane comprising PEG will prevent rejection of encapsulated cells during transplantation as taught by US Patent '914. Said type of biocompatible membrane can be used to substitute the different type of biocompatible membrane for successful implantation of insulin-producing cells in the method of treating diabetes taught by combined references of US Patent " 017, US Patent '764, US Patent' 194 and Posselt et al. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

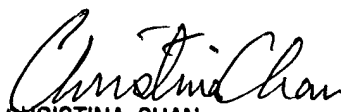
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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 6, 2005


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